radiopaque particles for contrast are between about 120μ and 350μ.

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 33-53 are pending after entry of the amendments set forth herein. Each of these claims was examined and rejected. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**" No new matter has been added.

Withdrawal of the previous Office Action in view of the present status of the application is acknowledged. In view of the present Office Action, Applicant respectfully requests reconsideration of the application in view of the amendments and remarks made herein.

35 USC §112

Claim 40-43 have been amended to handle the issued the Examiner noted in connection with claims 44 and 45. Withdrawal of the rejection against claims 44 and 45 is therefore requested.

35 USC §102(b) rejection of claims 40-45 over Ersek *et al* and Lawin *et al.*

Contrary to the Examiner's assertion, Ersek is not believed to present any teaching of using two discrete particle sizes. The text noted by the Examiner at col. 5 - line 64 - col. 6, line 2 merely discusses nominal variation of particles from a target size. Such variation of particle size is different from the situation expressed in claims 44 and 45. Claims 44 and 45 were not rejected in view of Lawin. Now, the limitations of claim 45 have been added to claim 40. Therefore claim 40 and those dependent thereon are believed to be allowable.

35 USC §103(a) rejection of claims 33-39 and 46 over Draenert *et al.* in view of Ersek *et al.*

With regard to claims 33-39 and 46 that Examiner has noted that Draenert does not disclose a composition that is injectable. While Ersek teaches the use of non micro-sized particles for purposes to do with particle interaction, the Examiner has provided no basis for modifying the composition in Draenert to one that is injectable as required by the rejected claims. Even though Draenert discloses forming a slurry, it is not an injectable slurry as required by the claims. Should the rejection be maintained, it is requested that a full *prima facie* case of obviousness be set forth in which some motivation for modification from the Draenert composition to one that is injectable be addressed. Otherwise withdrawal of the rejection is requested.

35 USC §103(a) rejection of claims 47-53 over Cooke *et al.* in view of Ersek *et al.*

It is asserted that the references the Examiner is attempting to combine are nonanalogous. In contrast to the situation in Ersek where the particles themselves provide the filler material, in the present invention, the hard tissue implant matrix is the "filler" whereas the particles are provided for their radiopacity. Simply put, Ersek and the present invention speak to different approaches and solutions for different problems. It is respectfully asserted that one seeking to improve hard tissue material implantation would not turn to Ersek for any reason. Applicant has previously distinguished the nature of hard tissue and soft tissue matrices in support of this proposition.

In addition, it is asserted that the motivation expressed by the Examiner with respect to using the teaching of Ersek in connection with Cooke (avoiding the adverse – physiological – effects of smaller particles (col. 3, line 60 – col. 4 line 44; col. 6, lines 8-12) and taking into account variation from patient to patient (col. 5 line 64 = col. 6, line 2)) is not applicable to the context of hard tissue implants.[1] In the context of hard tissue implantation, the use of very small particles - even micron-sized particles (*e.g.*, conventional contrast agent) - does not present a problem. In fact, none of claims 47-53 excludes the use of such particles in specifically calling for radiopaque particles between about 120 and about 2200 microns. The "open" nature of claim 47 (by virtue of the term comprising) allows for this possibility, as does the size range of particles noted in claim 53 which specifically calls for any size of particle up to 350 microns for contrast. For each of these reasons, the expressed motivation to avoid adverse physiological effects (macrophage engulfment as noted at col. 6, line 14 of the reference) is not pertinent.

What is more, there is no need to account for so-called patient variation by way of selecting a larger size range of particles for use in hard tissue implantation. This consideration simply has no applicability in the hard tissue implantation arena.

For these reasons, withdrawal of the rejections is requested. In the event the rejection is to be maintained, it is asserted that the Examiner should (at minimum) provide some evidence in support of the relevance of the expressed motivation(s) to utilize the teaching of Ersek as proposed.

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[1] Applicant fails to see any reference in Eresk or elsewhere that using larger particles would aid in actual injection. The only discussion cited by the Examiner in Eresk has to do with the resulting presence of small particles (*e.g.*, 60μ particles). Unless the Examiner can support such a consideration without using Applicants specification as a guide in that regard, using larger particles to aid in injection should be withdrawn as an asserted motivation.

Furthermore, with respect to claims 52 and 53 where at least two discrete ranges of particle sizes are required (as argued above with respect to the §102 rejection of claims under Ersek alone) no such teaching is believed to be expressed in the reference. Accordingly, these claims should be allowed, irrespective of the remarks immediately above. Should the Examiner continue to see the situation otherwise, a detailed explanation of her position is requested in order that Applicant may adequately judge the propriety of continuing the prosecution of the claims as they stand in accordance with 35 USC §132. Otherwise, withdrawal of the rejection is requested.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided. It is believed that this paper is fully responsive. In this case any issue remains, however, it is requested that the Examiner contact the undersigned in order that it may be handled expeditiously.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALX-002CON.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 12/19/02

By: _____
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

40. (Amended) An [enhanced visibility] injectable composition comprising:

a flowable matrix; [and]

radiopaque particles in said flowable matrix, said radiopaque particles having a size between about 350μ and about 2200μ so as to be individually visible during implantation, and

radiopaque particles for contrast having a particle size up to about 350μ.

41. (Amended) The [enhanced visibility] injectable composition of claim 40, wherein said radiopaque particles have a size between about 570μ and 2200μ.

42. (Amended) The [enhanced visibility] injectable composition of claim 40, wherein said radiopaque particles have a size between about 450μ and 1600μ.

43. (Amended) The [enhanced visibility] injectable composition of claim 40, wherein said radiopaque particles have a size between about 570μ and 1150μ.

44. (Amended) The injectable composition of claim 40, [further comprising:] wherein said radiopaque particles for contrast [having a particle size] are between about 120μ and 350μ.